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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/840,112

05/06/2004

Jaime Simon

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24573

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07/07/2009

K&L Gates LLP  
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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/840,112	<b>Applicant(s)</b> SIMON ET AL.	
	<b>Examiner</b> JAGADISHWAR R. SAMALA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of Applicant's Remarks filed on 03/11/2009.

- Claims 1-23 are pending in the instant application.

### Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 rejected under 35 U.S.C. 102(b) as being anticipated by Imondi et al (US 4,143,130) **are withdrawn**.
3. Claims 1-2 and 4-9 rejected under 35 U.S.C. 102(b) as being anticipated by Motoki Yonekawa et al (JP H10-130154) **are withdrawn**.

### Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1,4-6, 9,13 and 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al (US 4,470,975) **are withdrawn**.

6. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoki Yonekawa et al (JP 1410-130154) or Imondi et al (US 4,143,130) in view of Berger et al (US 4,470,975) **are withdrawn**.

However, upon further consideration, a new ground(s) of rejection is made as discussed below.

7. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al (US 4,470,975) and Thomas et al (US 5,004,603) in view of Samejima et al (EP 0077956).

Applicant claims are directed towards a method for increasing fluid loss through the feces in a host comprising the step of directly administering to the intestinal tract of the host an effective amount of a water-absorbent polymer for increasing the fluid in the feces, wherein the water-absorbent polymer is capable of absorbing at least 10 times its weight in physiological saline.

Berger discloses a composition and method of removing fluid or edema by diverting water elimination from the renal route to the gastrointestinal route, and removing excess water from the body by the gastrointestinal tract of an animal by

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administering to said animal a polysaccharide such as dextran (see abstract, column 1, line 54-56. and column 10, lines 5-30). The insoluble hydrophilic, cross- linked polysaccharides are capable of absorbing water with swelling, the water regain of the product being within the range of about 1 to 50 grams per gram of the dry gel product administered (see col. 4 lines, 34-59). In one embodiment (Fig, 1) illustrates that the water content of feces of rats treated with insoluble hydrophilic, cross- linked dextrans is significantly higher than that of untreated rats. These pharmacological properties are of significant therapeutic value in the treatment of edema, water intoxication in chronic renal failure, and in the treatment of other forms of fluid retention such as congestive heart failure, cirrhosis of the liver and other disorders associated with refractor swelling. Additional disclosure includes that the insoluble cross-linked polysaccharide polymer may be ingested by the patient and during passage of these substances through the digestive system, water is absorbed or bound tremendously and finally along with bound water, urea in the lumen of the gastrointestinal system is then eliminated by passage from the alimentary canal in the normal manner.

Thompson discloses a method of administering a composition to ruminants, such feeding composition comprising polymers derived from monomers such as (meth)acrylic acid and (meth)acrylamide that is capable of absorbing water and swell by a factor (w/w) of at least 10-50 times its weight (see column 3, lines 35-60)

Berger and Thompson meets claim limitation as discussed above but fails to enteric coat the water-absorbing polymer for directly administering to the intestinal tract of the host.

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Samejima discloses an enteric coated microcapsules containing an active component as core material, the coating walls of which consists essentially of ethylcellulose and an enteric polymeric material such as hydroxypropyl methylcellulose phthalate, copolymers of methacrylic acid or methacrylate (abstract and page 4 and 5). The core material includes cellulose, starch, carboxymethyl cellulose, cross-linked dextran, cross-linked polyacrylic acid, self-cross-linked methacrylic acid, which shows at least 1.2 times increase in weight (page 6 lines 1-10). Additional disclosure includes that the enteric coated microcapsules are capable of releasing easily the active component (core material) in intestinal tract while protecting the core material sufficiently in stomach.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate enteric coated microcapsule containing water-absorbing polymers into the Berger and Thompson composition. The person of ordinary skill in the art would have been motivated to make those modifications, because by coating the composition or capsule with enteric polymeric material, the capsules are not disintegrated in the stomach, wherein the active core material remain intact and are transported to the intestine, where they are released to perform the biological or pharmaceutical effects such as absorption of water from intestine and remove excess amounts of water from the body by the gastrointestinal route. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because Berger, Thompson and Samejima teaches a composition that can be used in same filed

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of endeavor, such as successfully removing excess fluid or water in a body by administering an effective amount of a water-absorbing polymer to the host.

8. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoki Yonekawa et al (JP H10-13-154) in view of Samejima et al (EP 0077956).

Applicant claims are directed towards a method for increasing fluid loss through the feces in a host comprising the step of directly administering to the intestinal tract of the host an effective amount of a water-absorbent polymer for increasing the fluid in the feces, wherein the water-absorbent polymer is capable of absorbing at least 10 times its weight in physiological saline.

Yonekawa discloses a method of oral administration of drug including acrylic acid type water absorbent polymers as the effective component of the drug. The acrylic acid water absorbent resins or polymer is capable of absorbing (volume (mL) of a physiological saline solution absorbed per one gm) is 5 to 100 times of its weight (0026). The acrylic acid type polymers include, acrylic acid metal salt type polymers, methacrylic acid type polymers and polymers that can graft polymerize with acrylic acid are for e.g., the hydrophilic poly saccharides such as starch, carrageenan, agarose, carboxy methyl cellulose and the like (0021). For oral administration, a general support material can be used to make it into an appropriate shape such as tablets, granules, capsules, and the like (0027).

Yonekawa meets claim limitation as discussed above but fails to enteric coat the water-absorbing polymer for directly administering to the intestinal tract of the host.

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Samejima discloses an enteric coated microcapsules containing an active component as core material, the coating walls of which consists essentially of ethylcellulose and an enteric polymeric material such as hydroxypropyl methylcellulose phthalate, copolymers of methacrylic acid or methacrylate (abstract and page 4 and 5). The core material includes cellulose, starch, carboxymethyl cellulose, cross-linked dextran, cross-linked polyacrylic acid, self-cross-linked methacrylic acid, which shows at least 1.2 times increase in weight (page 6 lines 1-10). Additional disclosure includes that the enteric coated microcapsules are capable of releasing easily the active component (core material) in intestinal tract while protecting the core material sufficiently in stomach.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate enteric coated microcapsule containing water-absorbing polymers into the Berger and Thompson composition. The person of ordinary skill in the art would have been motivated to make those modifications, because by coating the composition or capsule with enteric polymeric material, the capsules are not disintegrated in the stomach, wherein the active core material remain intact and are transported to the intestine, where they are released to perform the biological or pharmaceutical effects such as absorption of water from intestine and remove excess amounts of water from the body by the gastrointestinal route. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because Berger, Thompson and Samejima teaches a composition that can be used in same filed

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of endeavor, such as successfully removing excess fluid or water in a body by administering an effective amount of a water-absorbing polymer to the host.

### **Conclusion**

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/  
Primary Examiner, Art Unit 1618

Jagadishwar R Samala  
Examiner  
Art Unit 1618

sjr

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